(1) collecting a urinary or blood sample from the subject and separating the sample into a first portion and a second portion;

(2) performing the following steps (a) and (b) which may be performed in any order:

(a) (i) immobilizing capturing antibody on a solid matrix under conditions permitting binding of the capturing antibody to the solid matrix, wherein the capturing antibody specifically binds to an early pregnancy associated molecular isoform of human chorionic gonadotropin;

(ii) contacting the immobilized capturing antibody with the first portion of the sample obtained in step (1) under conditions permitting binding of the capturing antibody to the early pregnancy associated molecular isoform of human chorionic gonadotropin present in the sample so as to form a complex;

(iii) removing unbound sample from the complex;

(iv) contacting the complex with a detecting antibody which specifically binds to an early pregnancy associated molecular isoform of human chorionic gonadotropin, under conditions permitting binding of the detecting antibody to the human chorionic gonadotropin so as to form a complex;

(v) removing unbound detecting antibody;

(vi) determining the amount of detecting

antibody which binds to the complex;

(b) (i) immobilizing a capturing antibody on a solid matrix under conditions permitting binding of the capturing antibody to the solid matrix, wherein the capturing antibody specifically binds to intact non-nicked human chorionic gonadotropin;

(ii) contacting the immobilized capturing antibody with the second portion of the sample obtained in step (1) under conditions permitting binding of the capturing antibody to the intact non-nicked human chorionic gonadotropin present in the sample so as to form a complex;

(iii) removing unbound sample from the complex;

(iv) contacting the complex with detecting antibody which specifically binds to intact non-nicked human chorionic gonadotropin under conditions permitting binding of the detecting antibody to the human chorionic gonadotropin so as to form a complex;

(v) removing unbound detecting antibody;

(vi) determining the amount of detecting antibody which binds to the complex;

(3) comparing the amount of antibody measured in step (2)(a) with the amount of antibody measured in step (2)(b), so as to thereby determine a ratio of the amount of antibody measured in step (2)(a) with the amount of antibody

measured in step (2)(b);

(4) repeating steps (2) through (3) throughout the apparent pregnancy to determine a profile of the ratios, wherein a profile of ratios which do not diminish and are greater than 1.0 indicates that the subject is afflicted with gestational trophoblast malignancy.--

--68.(Amended) A method for detecting gestational trophoblast malignancy in a subject which comprises:

(1) collecting a urinary or blood sample from the subject and separating the sample into a first portion and a second portion;

(2) performing the following steps (a) and (b) which may be performed in any order:

(a) (i) immobilizing a capturing antibody on a solid matrix under conditions permitting binding of the capturing antibody to the solid matrix, wherein the capturing antibody specifically binds to an early pregnancy associated molecular isoform of human chorionic gonadotropin;

(ii) contacting the immobilized capturing antibody with the first portion of the sample obtained in step (1) under conditions permitting binding of the capturing antibody to the early pregnancy associated molecular isoform of human chorionic gonadotropin present in the sample so as to form a complex;

(iii) removing unbound sample from the complex;

(iv) determining the amount of early pregnancy

associated molecular isoform of human chorionic gonadotropin which is bound to the capturing antibody in the complex;

(b) (i) immobilizing a capturing antibody on a solid matrix under conditions permitting binding of the capturing antibody to the solid matrix, wherein the capturing antibody specifically binds to intact non-nicked human chorionic gonadotropin;

(ii) contacting the immobilized capturing antibody with the second portion of the sample obtained in step (1) under conditions permitting binding of the capturing antibody to the intact non-nicked human chorionic gonadotropin present in the sample so as to form a complex;

(iii) removing unbound sample from the complex;

(iv) determining the amount of intact non-nicked human chorionic gonadotropin which is bound to the capturing antibody in the complex;

(3) comparing the amount of early pregnancy associated molecular isoform of human chorionic gonadotropin measured in step (2)(a) with the amount of intact non-nicked human chorionic gonadotropin measured in step (2)(b), so as to thereby determine a ratio of the amount of early pregnancy associated molecular isoform of human chorionic gonadotropin measured in step (2)(a) measured in step (2)(a) with the amount of intact non-nicked human

chorionic gonadotropin measured in step (2)(b);

(4) repeating steps (2) through (3) throughout the apparent pregnancy to determine a profile of the ratios, wherein a profile of ratios which do not diminish and are greater than 1.0 indicates that the subject is afflicted with gestational trophoblast malignancy.--

--69.(Amended) A method for detecting gestational trophoblast malignancy in a subject which comprises:

(1) collecting a urinary or blood sample from the subject and separating the sample into a first portion and a second portion;

(2) performing the following steps (a) and (b) which may be performed in any order:

(a) (i) contacting the first portion of the sample obtained in step (1) with a capturing antibody which binds to an early pregnancy associated molecular isoform of human chorionic gonadotropin under conditions permitting binding of the capturing antibody to the early pregnancy associated molecular isoform of hCG present in the sample so as to form a complex;

(ii) removing unbound sample and unbound capturing antibody from the complex;

(iii) contacting the complex with a detecting antibody which specifically binds to an early pregnancy associated molecular isoform of human chorionic gonadotropin, under conditions permitting binding of

the detecting antibody to the human chorionic gonadotropin so as to form a complex;

(iv) removing unbound detecting antibody;

(v) determining the amount of detecting antibody which binds to the complex;

(b) (i) contacting the second portion of the sample obtained in step (1) with a capturing antibody which binds to intact non-nicked human chorionic gonadotropin under conditions permitting binding of the capturing antibody to the intact non-nicked human chorionic gonadotropin present in the sample so as to form a complex;

(ii) removing unbound sample and unbound capturing antibody from the complex;

(iii) contacting the complex with a detecting antibody which specifically binds to intact non-nicked human chorionic gonadotropin under conditions permitting binding of the detecting antibody to the human chorionic gonadotropin so as to form a complex;

(iv) removing unbound detecting antibody;

(v) determining the amount of detecting antibody which binds to the complex;

(3) comparing the amount of antibody measured in step (2)(a) with the amount of antibody measured in step (2)(b), so as to thereby determine a ratio of the amount of antibody

measured in step (2)(a) with the amount of antibody measured in step (2)(b);

(4) repeating steps (2) through (3) throughout the apparent pregnancy to determine a profile of the ratios, wherein a profile of ratios which do not diminish and are greater than 1.0 indicates that the subject is afflicted with gestational trophoblast malignancy.--

--70.(Amended) A method for detecting gestational trophoblast malignancy in a subject which comprises:

(1) collecting a urinary or blood sample from the subject and separating the sample into a first portion and a second portion;

(2) performing the following steps (a) and (b) which may be performed in any order:

(a) (i) contacting the first portion of the sample obtained in step (1) with a capturing antibody which binds to an early pregnancy associated molecular isoform of human chorionic gonadotropin under conditions permitting binding of the capturing antibody to the early pregnancy associated molecular isoform of human chorionic gonadotropin present in the sample so as to form a complex;

(ii) removing unbound sample and unbound capturing antibody from the complex;

(iii) determining the amount of early pregnancy associated molecular isoform of human chorionic gonadotropin which is bound to the capturing antibody in the complex;

(b) (i) contacting the second portion of the sample obtained in step (1) with a capturing antibody an intact non-nicked human chorionic gonadotropin under conditions permitting binding of the capturing antibody to the intact non-nicked human chorionic gonadotropin present in the sample so as to form a complex;

(ii) removing unbound sample and unbound capturing antibody from the complex;

(iii) determining the amount of intact non-nicked human chorionic gonadotropin which is bound to the capturing antibody in the complex;

(3) comparing the amount of early pregnancy associated molecular isoform of human chorionic gonadotropin measured in step (2)(a) with the amount of intact non-nicked human chorionic gonadotropin measured in step (2)(b), so as to thereby determine a ratio of the amount of early pregnancy associated molecular isoform of human chorionic gonadotropin measured in step (2)(a) measured in step (2)(a) with the amount of intact non-nicked human chorionic gonadotropin measured in step (2)(b);

(4) repeating steps (2) through (3) throughout the apparent pregnancy to determine a profile of the ratios, wherein a profile of ratios which do not diminish and are greater than 1.0 indicates that the subject is afflicted with gestational trophoblast malignancy.--

--71. (Amended) The method of any one of claims 67-70, wherein

the capturing antibody of step (2)(b) is B152 (ATCC Designation No. HB-12467).--

--72. (Amended) The method of any one of claims 67-70, wherein the capturing antibody of step (2)(a) is B109 is (ATCC Designation No. PTA-1624).--

--73. (Amended) The method of claim 67 or 69, wherein the detecting antibody of step (2)(b) is B207 (ATCC Designation No. PTA-1626).--

--74. (Amended) The method of claim 67 or 69, wherein the detecting antibody of step (2)(a) is B108 (ATCC Designation No. PTA-1625).--

REMARKS

Claims 67-80 are pending in the subject application. Applicants have herein canceled claim 77 without prejudice or disclaimer to their right to pursue the subject matter of this claim in a later-filed application. Applicant shave also herein amended claims 67-74. Support for these amendments may be found inter alia in the specification as follows: page 27, lines 20-21; page 63, lines 6-19; and Figure 5. This amendment does not involve any issue of new matter. Therefore, entry of this amendment is respectfully requested such that claims 67-76 and 78-80.

Priority

The Examiner stated that an application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the